



**Recommendations for Use of Antiretroviral Drugs in Pregnant HIV-1-Infected Women for Maternal Health and Interventions to Reduce Perinatal HIV Transmission in the United States**

Downloaded from <http://aidsinfo.nih.gov/guidelines> on 12/21/2016

Visit the AIDSinfo website to access the most up-to-date guideline.

Register for e-mail notification of guideline updates at <http://aidsinfo.nih.gov/e-news>.

## Appendix B: Safety and Toxicity of Individual Antiretroviral Agents in Pregnancy

**Table 8. Antiretroviral Drug Use in Pregnant HIV-Infected Women: Pharmacokinetic and Toxicity Data in Human Pregnancy and Recommendations for Use in Pregnancy<sup>a</sup>** (page 1 of 19)

Generic Name (Abbreviation) Trade Name	Formulation	Dosing Recommendations	Use in Pregnancy	Last Reviewed
<b>NNRTIs</b> NRTIs are recommended for use as part of combination regimens, usually including two NRTIs with either an NNRTI or one or more PIs. Use of single or dual NRTIs alone is not recommended for treatment of HIV infection. See text for discussion of potential maternal and infant mitochondrial toxicity.				
<b>Abacavir</b> (ABC) <i>Ziagen</i>  (ABC/3TC) <i>Epzicom</i>  (ABC/3TC/ZDV) <i>Trizivir</i>  (ABC/DTG/3TC) <i>Triumeq</i>	<u>ABC (Ziagen):</u> <u>Tablet:</u> • 300 mg  <u>Solution:</u> • 20 mg/mL  <u>Epzicom:</u> • ABC 600 mg plus 3TC 300-mg tablet  <u>Trizivir:</u> • ABC 300 mg plus 3TC 150 mg plus ZDV 300-mg tablet  <u>Triumeq:</u> • ABC 600 mg plus DTG 50 mg plus 3TC 300-mg tablet	<u>Standard Adult Doses:</u> <u>ABC (Ziagen):</u> • 300 mg twice daily or 600 mg once daily, without regard to food  <u>Epzicom:</u> • 1 tablet once daily without regard to food  <u>Trizivir:</u> • 1 tablet twice daily without regard to food  <u>Triumeq:</u> • 1 tablet daily without regard to food  <u>PK in Pregnancy:</u> • PK not significantly altered in pregnancy.  <u>Dosing in Pregnancy:</u> • No change in dose indicated.	High placental transfer to fetus. <sup>b</sup> No evidence of human teratogenicity (can rule out 2-fold increase in overall birth defects).  Hypersensitivity reactions occur in approximately 5% to 8% of non-pregnant individuals; a much smaller percentage are fatal and are usually associated with re-challenge. Rate in pregnancy is unknown. Testing for HLA-B*5701 identifies patients at risk of reactions and should be done and documented as negative before starting ABC. Patients should be educated regarding symptoms of hypersensitivity reaction.	April 29, 2016
<b>Didanosine</b> (ddI) <i>Videx</i> <i>Videx EC</i>	<u>ddI (Videx)</u> <u>Buffered Tablets (Non-EC):</u> • No longer available  <u>Solution:</u> • 10 mg/mL oral solution  <u>Videx EC (EC Beadlets) Capsules:</u> • 125 mg • 200 mg • 250 mg • 400 mg  <u>Generic Delayed-Release Capsules:</u> • 200 mg • 250 mg • 400 mg	<u>Standard Adult Doses</u> <u>Body Weight ≥60 kg:</u> • 400 mg once daily  <u>With TDF:</u> • 250 mg once daily; take 1/2 hour before or 2 hours after a meal.  <u>Body Weight &lt;60kg:</u> • 250 mg once daily  <u>With TDF:</u> • 200 mg once daily; take 1/2 hour before or 2 hours after a meal.  <b>Note:</b> Preferred dosing with oral solution is twice daily (total daily dose divided into 2 doses); take 1/2 hour before or 2 hours after a meal.	Low-moderate placental transfer to fetus. <sup>b</sup> In the Antiretroviral Pregnancy Registry, an increased rate of birth defects with ddI compared to general population was noted after both first-trimester (20/423, 4.7%; 95% CI, 2.9% to 7.2%) and later exposure (20/461, 4.3%; 95% CI 2.7% to 6.6%). No specific pattern of defects was noted and clinical relevance is uncertain.  ddI <b>should not be used</b> with d4T. Lactic acidosis, sometimes fatal, has been reported in pregnant women receiving ddI and d4T together.	April 29, 2016

**Table 8. Antiretroviral Drug Use in Pregnant HIV-Infected Women: Pharmacokinetic and Toxicity Data in Human Pregnancy and Recommendations for Use in Pregnancy<sup>a</sup>** (page 2 of 19)

Generic Name (Abbreviation) Trade Name	Formulation	Dosing Recommendations	Use in Pregnancy	Last Reviewed
		<p><u>PK in Pregnancy:</u></p> <ul style="list-style-type: none"> <li>• PK not significantly altered in pregnancy.</li> </ul> <p><u>Dosing in Pregnancy:</u></p> <ul style="list-style-type: none"> <li>• No change in dose indicated.</li> </ul>		
<b>Emtricitabine</b> (FTC) <i>Emtriva</i>  (FTC/TDF) <i>Truvada</i>  (FTC/TDF/EFV) <i>Atripla</i>  (FTC/TDF/RPV) <i>Complera</i>  (FTC/TDF/EVG/COBI) <i>Stribild</i>  (FTC/TAF/RPV) <i>Odefsey</i>  (FTC/TAF/EVG/COBI) <i>Genvoya</i>	<p><u>Emtriva (FTC)</u></p> <p><u>Capsules:</u></p> <ul style="list-style-type: none"> <li>• 200 mg</li> </ul> <p><u>Oral Solution:</u></p> <ul style="list-style-type: none"> <li>• 10 mg/mL</li> </ul> <p><u>Truvada:</u></p> <ul style="list-style-type: none"> <li>• FTC 200 mg plus TDF 300 mg tablet</li> </ul> <p><u>Atripla:</u></p> <ul style="list-style-type: none"> <li>• FTC 200 mg plus TDF 300 mg plus EFV<sup>c</sup> 600 mg tablet</li> </ul> <p><u>Complera:</u></p> <ul style="list-style-type: none"> <li>• FTC 200 mg plus TDF 300 mg plus RPV 25 mg tablet</li> </ul> <p><u>Stribild:</u></p> <ul style="list-style-type: none"> <li>• FTC 200 mg plus TDF 300 mg plus EVG 150 mg plus COBI 150 mg tablet</li> </ul> <p><u>Odefsey:</u></p> <ul style="list-style-type: none"> <li>• FTC 200 mg plus TAF 25 mg plus RPV 25 mg tablet</li> </ul> <p><u>Genvoya:</u></p> <ul style="list-style-type: none"> <li>• FTC 200 mg plus TAF 10 mg plus EVG 150 mg plus COBI 150 mg tablet</li> </ul>	<p><u>Standard Adult Dose(s)</u></p> <p><u>Emtriva (FTC)</u></p> <p><u>Capsule:</u></p> <ul style="list-style-type: none"> <li>• 200 mg once daily without regard to food</li> </ul> <p><u>Oral Solution:</u></p> <ul style="list-style-type: none"> <li>• 240 mg (24 mL) once daily without regard to food</li> </ul> <p><u>Truvada:</u></p> <ul style="list-style-type: none"> <li>• 1 tablet once daily without regard to food</li> </ul> <p><u>Atripla:</u></p> <ul style="list-style-type: none"> <li>• 1 tablet once daily at or before bedtime. Take on an empty stomach to reduce side effects.</li> </ul> <p><u>Complera:</u></p> <ul style="list-style-type: none"> <li>• 1 tablet once daily with food</li> </ul> <p><u>Stribild:</u></p> <ul style="list-style-type: none"> <li>• 1 tablet once daily with food</li> </ul> <p><u>Odefsey:</u></p> <ul style="list-style-type: none"> <li>• 1 tablet once daily with food</li> </ul> <p><u>Genvoya:</u></p> <ul style="list-style-type: none"> <li>• 1 tablet once daily with food</li> </ul> <p><u>PK in Pregnancy:</u></p> <ul style="list-style-type: none"> <li>• PK of FTC not significantly altered in pregnancy.</li> </ul> <p><u>Dosing in Pregnancy:</u></p> <ul style="list-style-type: none"> <li>• No change in FTC dose indicated.</li> </ul>	<p>High placental transfer to fetus.<sup>b</sup></p> <p>No evidence of human teratogenicity (can rule out 2-fold increase in overall birth defects).</p> <p>If HBV-coinfected, it is possible that a HBV flare may occur if the drug is stopped; see <a href="#">HIV/Hepatitis B Virus Coinfection</a>.</p>	June 7, 2016

**Table 8. Antiretroviral Drug Use in Pregnant HIV-Infected Women: Pharmacokinetic and Toxicity Data in Human Pregnancy and Recommendations for Use in Pregnancy<sup>a</sup>** (page 3 of 19)

Generic Name (Abbreviation) Trade Name	Formulation	Dosing Recommendations	Use in Pregnancy	Last Reviewed
<b>Lamivudine</b> (3TC) <i>EpiVir</i>  (3TC/ZDV) <i>Combivir</i>  (3TC/ABC) <i>Epzicom</i>  (3TC/ZDV/ABC) <i>Trizivir</i>  (3TC/ABC/DTG) <i>Triumeq</i>	<u>3TC (EpiVir)</u> <u>Tablets:</u> <ul style="list-style-type: none"> <li>• 150 mg</li> <li>• 300 mg</li> </ul> <u>Oral Solution:</u> <ul style="list-style-type: none"> <li>• 10 mg/mL</li> </ul> <u>Combivir:</u> <ul style="list-style-type: none"> <li>• 3TC 150 mg plus ZDV 300 mg tablet</li> </ul> <u>Epzicom:</u> <ul style="list-style-type: none"> <li>• 3TC 300 mg plus ABC 600 mg tablet</li> </ul> <u>Trizivir:</u> <ul style="list-style-type: none"> <li>• 3TC 150 mg plus ZDV 300 mg plus ABC 300 mg tablet</li> </ul> <u>Triumeq:</u> <ul style="list-style-type: none"> <li>• 3TC 300 mg plus ABC 600 mg plus DTG 50-mg <b>tablet</b></li> </ul>	<u>Standard Adult Dose(s)</u> <u>3TC (Lamivudine):</u> <ul style="list-style-type: none"> <li>• 150 mg twice daily or 300 mg once daily, without regard to food</li> </ul> <u>Combivir:</u> <ul style="list-style-type: none"> <li>• 1 tablet twice daily without regard to food</li> </ul> <u>Epzicom:</u> <ul style="list-style-type: none"> <li>• 1 tablet once daily without regard to food</li> </ul> <u>Trizivir:</u> <ul style="list-style-type: none"> <li>• 1 tablet twice daily without regard to food</li> </ul> <u>Triumeq:</u> <ul style="list-style-type: none"> <li>• 1 tablet once daily without regard to food</li> </ul> <u>PK in Pregnancy:</u> <ul style="list-style-type: none"> <li>• PK not significantly altered in pregnancy.</li> </ul> <u>Dosing in Pregnancy:</u> <ul style="list-style-type: none"> <li>• No change in dose indicated.</li> </ul>	High placental transfer to fetus. <sup>b</sup>  No evidence of human teratogenicity (can rule out 1.5-fold increase in overall birth defects).  If HBV-coinfected, it is possible that an HBV flare may occur if the drug is stopped; see <a href="#">HIV/Hepatitis B Virus Coinfection</a> .	June 7, 2016
<b>Stavudine</b> (d4T) <i>Zerit</i>	<u>d4T (Zerit)</u> <u>Capsules:</u> <ul style="list-style-type: none"> <li>• 15 mg</li> <li>• 20 mg</li> <li>• 30 mg</li> <li>• 40 mg</li> </ul> <u>Oral Solution:</u> <ul style="list-style-type: none"> <li>• 1 mg/mL following reconstitution</li> </ul>	<u>Standard Adult Dose(s)<sup>d</sup></u> <u>Body Weight ≥60 kg:</u> <ul style="list-style-type: none"> <li>• 40 mg twice daily without regard to meals</li> </ul> <u>Body Weight &lt;60 kg:</u> <ul style="list-style-type: none"> <li>• 30 mg twice daily without regard to meals</li> </ul> <u>PK in Pregnancy:</u> <ul style="list-style-type: none"> <li>• PK not significantly altered in pregnancy.</li> </ul> <u>Dosing in Pregnancy:</u> <ul style="list-style-type: none"> <li>• No change in dose indicated.</li> </ul>	High placental transfer. <sup>b</sup>  No evidence of human teratogenicity (can rule out 2-fold increase in overall birth defects).  d4T should not be used with ddI or ZDV.  Lactic acidosis, sometimes fatal, has been reported in pregnant women receiving ddI and d4T together.	June 7, 2016

**Table 8. Antiretroviral Drug Use in Pregnant HIV-Infected Women: Pharmacokinetic and Toxicity Data in Human Pregnancy and Recommendations for Use in Pregnancy<sup>a</sup>** (page 4 of 19)

Generic Name (Abbreviation) Trade Name	Formulation	Dosing Recommendations	Use in Pregnancy	Last Reviewed
<b>Tenofovir Alafenamide (TAF)</b>  (TAF/FTC/EVG/COBI) <i>Genvoya</i>  (TAF/FTC/RPV) <i>Odefsey</i>  (TAF/FTC) <i>Descovy</i>	<u>Genvoya:</u> • TAF 10 mg plus FTC 200 mg plus EVG 150 mg plus COBI 150 mg tablet  <u>Odefsey:</u> • TAF 25 mg plus FTC 200 mg plus RPV 25 mg tablet  <u>Descovy:</u> • TAF 25 mg plus FTC 200 mg tablet	<u>Standard Adult Dose</u> <i>Genvoya, Odefsey:</i> • 1 tablet once daily with food  <i>Descovy:</i> • 1 tablet once daily with or without food • Same dose (TAF 25 mg) can be used with or without pharmacoenhancers  <u>PK in Pregnancy:</u> • No PK studies in human pregnancy  <u>Dosing in Pregnancy:</u> • Insufficient data to make dosing recommendation	No data on placental transfer of TAF are available.  Insufficient data to assess for teratogenicity in humans. No evidence of teratogenicity in rats.  Renal function should be monitored because of potential for renal toxicity.	October 26, 2016
<b>Tenofovir Disoproxil Fumarate (TDF)</b> <i>Viread</i>  (TDF/FTC) <i>Truvada</i>  (TDF/FTC/EFV) <i>Atripla</i>  (TDF/FTC/RPV) <i>Complera</i>  (TDF/FTC/EVG/COBI) <i>Stribild</i>	<u>TDF (Viread)</u> <u>Tablet:</u> • 300 mg  <u>Powder:</u> • 40 mg/1 g oral powder  <u>Truvada:</u> • TDF 300 mg plus FTC 200 mg tablet  <u>Atripla:</u> • TDF 300 mg plus FTC 200 mg plus EFV <sup>c</sup> 600 mg tablet  <u>Complera:</u> • TDF 300 mg plus FTC 200 mg plus RPV 25 mg tablet  <u>Stribild:</u> • TDF 300 mg plus FTC 200 mg plus EVG 150 mg plus COBI 150 mg tablet	<u>Standard Adult Dose</u> <i>TDF (Viread)</i> <u>Tablet:</u> • 300 mg once daily without regard to food  <u>Powder:</u> • 8 mg/kg (up to maximum 300 mg), take with food  <i>Truvada:</i> • 1 tablet once daily without regard to food  <i>Atripla:</i> • 1 tablet once daily at or before bedtime. Take on an empty stomach to reduce side effects.  <i>Complera:</i> • 1 tablet once daily with food  <i>Stribild:</i> • 1 tablet once daily with food  <u>PK in Pregnancy:</u> • AUC lower in third trimester than postpartum but trough levels adequate  <u>Dosing in Pregnancy:</u> • No change in dose indicated.	High placental transfer to fetus. <sup>b</sup>  No evidence of human teratogenicity (can rule out 1.5-fold increase in overall birth defects).  Studies in monkeys (at doses approximately 2-fold higher than that for human therapeutic use) show decreased fetal growth and reduction in fetal bone porosity within 2 months of starting maternal therapy. Human studies demonstrate no effect on intrauterine growth, but data are conflicting about potential effects on growth outcomes later in infancy.  If HBV-coinfected, it is possible that an HBV flare may occur if TDF is stopped; see <a href="#">HIV/Hepatitis B Virus Coinfection</a> .  Renal function should be monitored because of potential for renal toxicity.	June 7, 2016

**Table 8. Antiretroviral Drug Use in Pregnant HIV-Infected Women: Pharmacokinetic and Toxicity Data in Human Pregnancy and Recommendations for Use in Pregnancy<sup>a</sup>** (page 5 of 19)

Generic Name (Abbreviation) Trade Name	Formulation	Dosing Recommendations	Use in Pregnancy	Last Reviewed
<b>Zidovudine</b> (ZDV, AZT) <i>Retrovir</i>  (ZDV/3TC) <i>Combivir</i>  (ZDV/3TC/ABC) <i>Trizivir</i>	<u>ZDV (Retrovir)</u>  <u>Capsule:</u> <ul style="list-style-type: none"> <li>• 100 mg</li> </ul> <u>Tablet:</u> <ul style="list-style-type: none"> <li>• 300 mg</li> </ul> <u>Oral Solution:</u> <ul style="list-style-type: none"> <li>• 10 mg/mL</li> </ul> <u>Intravenous Solution:</u> <ul style="list-style-type: none"> <li>• 10 mg/mL</li> </ul> <u>Combivir:</u> <ul style="list-style-type: none"> <li>• ZDV 300 mg plus 3TC 150 mg tablet</li> </ul> <u>Trizivir:</u> <ul style="list-style-type: none"> <li>• ZDV 300 mg plus 3TC 150 mg plus ABC 300 mg tablet</li> </ul>	<u>Standard Adult Dose(s)</u>  <u>ZDV (Retrovir):</u> <ul style="list-style-type: none"> <li>• 300 mg BID or 200 mg TID, without regard to food</li> </ul> <u>Active Labor:</u> <ul style="list-style-type: none"> <li>• 2 mg/kg IV loading dose, followed by 1 mg/kg/hour continuous infusion from beginning of active labor until delivery</li> </ul> <u>Combivir:</u> <ul style="list-style-type: none"> <li>• One tablet twice daily, without regard to food</li> </ul> <u>Trizivir:</u> <ul style="list-style-type: none"> <li>• One tablet twice daily, without regard to food</li> </ul> <u>PK in Pregnancy:</u> <ul style="list-style-type: none"> <li>• PK not significantly altered in pregnancy.</li> </ul> <u>Dosing in Pregnancy:</u> <ul style="list-style-type: none"> <li>• No change in dose indicated.</li> </ul>	High placental transfer to fetus. <sup>b</sup>  No evidence of human teratogenicity (can rule out 1.5-fold increase in overall birth defects).	October 26, 2016

**Table 8. Antiretroviral Drug Use in Pregnant HIV-Infected Women: Pharmacokinetic and Toxicity Data in Human Pregnancy and Recommendations for Use in Pregnancy<sup>a</sup>** (page 6 of 19)

Generic Name (Abbreviation) Trade Name	Formulation	Dosing Recommendations	Use in Pregnancy	Last Reviewed
<b>NNRTI</b> NNRTIs are recommended for use in combination regimens with 2 NRTI drugs. Hypersensitivity reactions, including hepatic toxicity and rash, more common in women; unclear if increased in pregnancy.				
<b>Efavirenz</b> (EFV) <i>Sustiva</i> (EFV/TDF/FTC) <i>Atripla</i>	<u>EFV (Sustiva)</u> <i>Capsules:</i> • 50 mg • 200 mg <i>Tablet:</i> • 600 mg <u>Atripla:</u> • EFV 600 mg plus TDF 300 mg plus FTC 200 mg tablet	<u>Standard Adult Dose</u> <i>EFV (Sustiva):</i> • 600 mg once daily at or before bedtime, on empty stomach to reduce side effects <i>Atripla:</i> • 1 tablet once daily at or before bedtime, on empty stomach to reduce side effects <u>PK in Pregnancy:</u> • AUC decreased during third trimester, compared with postpartum, but nearly all third-trimester participants exceeded target exposure. <u>Dosing in Pregnancy:</u> • No change in dose indicated.	Moderate placental transfer to fetus. <sup>b</sup> Potential fetal safety concern: cynomolgus monkeys receiving EFV during the first trimester at a dose resulting in plasma levels comparable to systemic human therapeutic exposure had 3 of 20 infants with significant CNS or other malformations. In humans, there is no increase in overall birth defects with first-trimester EFV exposure. However, in humans with first-trimester exposure, there have been 6 retrospective case reports and 1 prospective case report of CNS defects and 1 prospective case report of anophthalmia with facial clefts. The relative risk with first-trimester exposure is unclear. Non-pregnant women of childbearing potential should undergo pregnancy testing before EFV initiation and counseling about potential risk to the fetus and desirability of avoiding pregnancy while on EFV-containing regimens. Alternate ARV regimens that do not include EFV should be strongly considered in women who are planning to become pregnant or who are sexually active and not using effective contraception. Because the risk of neural tube defects is restricted to the first 5–6 weeks of pregnancy and pregnancy is rarely recognized before 4–6 weeks, and unnecessary ARV drug changes during pregnancy may be associated with loss of viral control and increased risk of perinatal transmission, EFV may be continued in pregnant women receiving an EFV-based regimen who present for antenatal care in the first trimester (see <a href="#">HIV-Infected Pregnant Women Who are Currently Receiving Antiretroviral Treatment</a> ).	October 26, 2016



**Table 8. Antiretroviral Drug Use in Pregnant HIV-Infected Women: Pharmacokinetic and Toxicity Data in Human Pregnancy and Recommendations for Use in Pregnancy<sup>a</sup>** (page 7 of 19)

Generic Name (Abbreviation) Trade Name	Formulation	Dosing Recommendations	Use in Pregnancy	Last Reviewed
<b>Etravirine</b> (ETR) <i>Intelence</i>	<p>Tablets:</p> <ul style="list-style-type: none"> <li>• 25 mg</li> <li>• 100 mg</li> <li>• 200 mg</li> </ul> <p>For patients unable to swallow tablets whole, the tablets may be dispersed in a glass of water.</p>	<p><u>Standard Adult Dose(s):</u></p> <ul style="list-style-type: none"> <li>• 200 mg twice daily with food</li> </ul> <p><u>PK in Pregnancy:</u></p> <ul style="list-style-type: none"> <li>• PK data in pregnancy (n = 26) suggest 1.2–1.6 fold increased etravirine exposure during pregnancy.</li> </ul> <p><u>Dosing in Pregnancy:</u></p> <ul style="list-style-type: none"> <li>• No change in dose indicated.</li> </ul>	<p>Variable placental transfer, usually in the moderate to high categories, ranging from 0.19–4.25 (data from 18 mother-infant pairs).<sup>b</sup></p> <p>Insufficient data to assess for teratogenicity in humans. No evidence of teratogenicity in rats or rabbits.</p>	April 29, 2016
<p><b>Nevirapine</b> (NVP) <i>Viramune</i> <i>Viramune XR</i> (Extended Release)</p> <p><b>Note:</b> Generic available for all formulations</p>	<p><u>NVP (Viramune)</u></p> <p>Tablets:</p> <ul style="list-style-type: none"> <li>• 200 mg</li> </ul> <p><u>Oral Suspension:</u></p> <ul style="list-style-type: none"> <li>• 50 mg/5 mL</li> </ul> <p><u>Viramune XR Tablets:</u></p> <ul style="list-style-type: none"> <li>• 100 mg</li> <li>• 400 mg</li> </ul>	<p><u>Standard Adult Dose:</u></p> <ul style="list-style-type: none"> <li>• 200 mg once daily Viramune immediate release for 14 days (lead-in period); thereafter, 200 mg twice daily or 400 mg (Viramune XR tablet) once daily, without regard to food.</li> <li>• Repeat lead-in period if therapy is discontinued for &gt;7 days.</li> <li>• In patients who develop mild-to-moderate rash without constitutional symptoms during lead-in, continue lead-in dosing until rash resolves, but ≤28 days total.</li> </ul> <p><u>PK in Pregnancy:</u></p> <ul style="list-style-type: none"> <li>• PK not significantly altered in pregnancy.</li> </ul> <p><u>Dosing in Pregnancy:</u></p> <ul style="list-style-type: none"> <li>• No change in dose indicated.</li> </ul>	<p>High placental transfer to fetus.<sup>b</sup></p> <p>No evidence of human teratogenicity (can rule out 1.5-fold increase in overall birth defects and 2-fold increase in risk of birth defects in more common classes, cardiovascular and genitourinary).</p> <p>Increased risk of symptomatic, often rash-associated, and potentially fatal liver toxicity among women with CD4 counts ≥250/mm<sup>3</sup> when first initiating therapy; pregnancy does not appear to increase risk.</p> <p>NVP should be initiated in pregnant women with CD4 cell counts ≥250 cells/mm<sup>3</sup> only if benefit clearly outweighs risk because of potential increased risk of life-threatening hepatotoxicity in women with high CD4 cell counts. Elevated transaminase levels at baseline may increase the risk of NVP toxicity.</p> <p>Women who become pregnant while taking NVP-containing regimens and are tolerating them well can continue therapy, regardless of CD4 cell count.</p>	June 7, 2016



**Table 8. Antiretroviral Drug Use in Pregnant HIV-Infected Women: Pharmacokinetic and Toxicity Data in Human Pregnancy and Recommendations for Use in Pregnancy<sup>a</sup>** (page 8 of 19)

Generic Name (Abbreviation) Trade Name	Formulation	Dosing Recommendations	Use in Pregnancy	Last Reviewed
<b>Rilpivirine</b> (RPV) <i>Edurant</i>  (RPV/TDF/FTC) <i>Complera</i>	<u>RPV (Edurant)</u> <i>Tablets:</i> • 25 mg  <u>Complera:</u> • RPV 25 mg plus TDF 300 mg plus FTC 200 mg tablet	<u>Standard Adult Dose</u> <i>RPV (Edurant):</i> • 25 mg once daily with food  <i>Complera:</i> • 1 tablet once daily with food  <u>PK in Pregnancy:</u> • RPV PK highly variable during pregnancy. RPV AUC and trough concentration reduced 20% to 30% in pregnancy compared with postpartum, but <b>most</b> pregnant women exceeded target exposure.  <u>Dosing in Pregnancy:</u> • Routine dosing adjustment in all women is not recommended for RPV during pregnancy. Individual patients should be closely monitored.	Moderate to high placental transfer to fetus. <sup>b</sup>  No evidence of teratogenicity in rats or rabbits. Insufficient data to assess for teratogenicity in humans.	<b>June 7, 2016</b>

**Table 8. Antiretroviral Drug Use in Pregnant HIV-Infected Women: Pharmacokinetic and Toxicity Data in Human Pregnancy and Recommendations for Use in Pregnancy<sup>a</sup>** (page 9 of 19)

Generic Name (Abbreviation) Trade Name	Formulation	Dosing Recommendations	Use in Pregnancy	Last Reviewed
<b>PIs</b> PIs are recommended for use in combination regimens with 2 NRTI drugs. Hyperglycemia, new onset or exacerbation of diabetes mellitus, and diabetic ketoacidosis reported with PI use; unclear if pregnancy increases risk. Conflicting data regarding preterm delivery in women receiving PIs (see <a href="#">Combination Antiretroviral Drug Regimens and Pregnancy Outcomes</a> ).				
<b>Atazanavir</b> (ATV) <i>Reyataz</i>  <b>Note:</b> Must be combined with low-dose RTV boosting in pregnancy  <b>Atazanavir/Cobicistat</b> (ATV/COBI) <i>Evotaz</i>	<u>ATZ (Reyataz)</u> <u>Capsules:</u> • 150 mg • 200 mg • 300 mg  <u>Oral Powder:</u> • 50 mg packet  <u>Evotaz:</u> • ATV 300 mg plus COBI 150 mg tablet	Standard Adult Dose <u>ATZ (Reyataz)</u> <i>ARV-Naive Patients</i> <u>Without RTV Boosting:</u> • ATV 400 mg once daily with food; ATV without RTV boosting <b>is not recommended</b> when used with TDF, H <sub>2</sub> -receptor antagonists, or PPIs, or during pregnancy.  <u>With RTV Boosting:</u> • ATV 300 mg plus RTV 100 mg once daily with food • When combined with EFV in ARV-naive patients: ATV 400 mg plus RTV 100 mg once daily with food  <i>ARV-Experienced Patients:</i> • ATV 300 mg plus RTV 100 mg once daily with food • Do not use with PPIs or EFV. • If combined with an H <sub>2</sub> -receptor antagonist: ATV 300 mg plus RTV 100 mg once daily with food • If combined with an H <sub>2</sub> -receptor antagonist and TDF: ATV 400 mg plus RTV 100 mg once daily with food  <u>Powder Formulation:</u> • Oral powder is taken once daily with food at the same recommended adult dosage as the capsules along with ritonavir.  <u>Evotaz:</u> • One tablet once daily with food.  <u>PK in Pregnancy</u> <u>Atazanavir (Reyataz):</u> • ATV concentrations reduced during pregnancy; further reduced when given concomitantly with TDF or H <sub>2</sub> -receptor antagonist.  <u>Evotaz:</u> • No PK studies in human pregnancy.	Low placental transfer to fetus. <sup>b</sup>  No evidence of human teratogenicity (can rule out 1.5-fold increase in overall birth defects).  Must be given as low-dose RTV-boosted regimen in pregnancy.  Effect of <i>in utero</i> ATV exposure on infant indirect bilirubin levels is unclear. Non-pathologic elevations of neonatal hyperbilirubinemia have been observed in some but not all clinical trials to date.  Oral powder (but <b>not</b> capsules) contains phenylalanine, which can be harmful to patients with phenylketonuria.	June 7, 2016

**Table 8. Antiretroviral Drug Use in Pregnant HIV-Infected Women: Pharmacokinetic and Toxicity Data in Human Pregnancy and Recommendations for Use in Pregnancy<sup>a</sup>** (page 10 of 19)

Generic Name (Abbreviation) Trade Name	Formulation	Dosing Recommendations	Use in Pregnancy	Last Reviewed
		<p><u>Dosing in Pregnancy</u>  <i>Atazanavir (Reyataz):</i></p> <ul style="list-style-type: none"> <li>• Use of unboosted ATV <b>is not recommended</b> during pregnancy.</li> <li>• Use of ATV not recommended for treatment-experienced pregnant women taking TDF <b>and</b> an H<sub>2</sub>-receptor antagonist.</li> <li>• Use of an increased dose (400 mg ATV plus 100 mg RTV once daily with food) during the second and third trimesters results in plasma concentrations equivalent to those in non-pregnant adults on standard dosing. Although some experts recommend increased ATV dosing in all women during the second and third trimesters, the package insert recommends increased ATV dosing only for ARV-experienced pregnant women in the second and third trimesters also receiving either TDF or an H<sub>2</sub>-receptor antagonist.</li> </ul> <p><i>Evotaz:</i></p> <ul style="list-style-type: none"> <li>• Insufficient data to make dosing recommendation.</li> </ul>		June 7, 2016
<p><b>Darunavir</b> (DRV) <i>Prezista</i></p> <p><b>Note:</b> Must be combined with low-dose ritonavir (RTV) or cobicistat (COBI) boosting</p> <p><b>Darunavir/Cobicistat</b> (DRV/COBI) <i>Prezcobix</i></p>	<p><u>DRV (Prezista):</u></p> <ul style="list-style-type: none"> <li>• 75 mg</li> <li>• 150 mg</li> <li>• 600 mg</li> <li>• 800 mg</li> </ul> <p><u>Oral Suspension:</u></p> <ul style="list-style-type: none"> <li>• 100 mg/mL</li> </ul> <p><u>Prezcobix (Co-Formulated):</u></p> <ul style="list-style-type: none"> <li>• DRV 800 mg plus COBI 150 mg</li> </ul>	<p><u>Standard Adult Dose</u>  <i>ARV-Naïve Patients:</i></p> <ul style="list-style-type: none"> <li>• DRV 800 mg plus RTV 100 mg once daily with food</li> <li>• DRV 800 mg plus COBI 150 mg once daily with food</li> </ul> <p><i>ARV-Experienced Patients:</i></p> <p><u>If No DRV Resistance Mutations:</u></p> <ul style="list-style-type: none"> <li>• DRV 800 mg plus RTV 100 mg once daily with food</li> <li>• DRV 800 mg plus COBI 150 mg once daily with food</li> </ul> <p><u>If Any DRV Resistance Mutations:</u></p> <ul style="list-style-type: none"> <li>• DRV 600 mg plus RTV 100 mg twice daily with food</li> </ul> <p><u>PK in Pregnancy:</u></p> <ul style="list-style-type: none"> <li>• Decreased exposure in pregnancy with use of DRV/RTV.</li> </ul> <p><u>Dosing in Pregnancy:</u></p> <ul style="list-style-type: none"> <li>• Once-daily dosing with DRV/RTV <b>is not recommended</b> during pregnancy. Twice-daily DRV/RTV dosing (<b>DRV 600 mg plus RTV 100 mg with food</b>) recommended for all pregnant women. Increased twice-daily DRV dose (DRV 800 mg plus RTV 100 mg with food) during pregnancy <b>does not result in an increase in darunavir exposure and is not recommended.</b></li> <li>• No pregnancy PK/safety data for DRV/COBI co-formulation, so not recommended for use in pregnancy.</li> </ul>	<p>Low placental transfer to fetus.<sup>b</sup></p> <p>No evidence of teratogenicity in mice, rats, or rabbits. No evidence of human teratogenicity.</p> <p>Must be given as low-dose, RTV-boosted regimen.</p>	October 26, 2016

**Table 8. Antiretroviral Drug Use in Pregnant HIV-Infected Women: Pharmacokinetic and Toxicity Data in Human Pregnancy and Recommendations for Use in Pregnancy<sup>a</sup>** (page 11 of 19)

Generic Name (Abbreviation) Trade Name	Formulation	Dosing Recommendations	Use in Pregnancy	Last Reviewed
<b>Fosamprenavir</b> (FPV) <i>Lexiva (a prodrug of amprenavir)</i>  <b>Note:</b> Must be combined with low-dose RTV boosting in pregnancy	<u>Tablets:</u> • 700 mg  <u>Oral Suspension:</u> • 50 mg/mL	<u>Standard Adult Dose</u> <i>ARV-Naive Patients:</i> • FPV 1400 mg twice daily without food, <i>or</i> • FPV 1400 mg plus RTV 100 or 200 mg once daily without food, <i>or</i> • FPV 700 mg plus RTV 100 mg twice daily without food  <i>PI-Experienced Patients (Once-Daily Dosing Not Recommended):</i> • FPV 700 mg plus RTV 100 mg twice daily without food  <i>Co-Administered with EFV:</i> • FPV 700 mg plus RTV 100 mg twice daily without food; <i>or</i> • FPV 1400 mg plus RTV 300 mg once daily without food  <u>PK in Pregnancy:</u> • With RTV boosting, AUC is reduced during the third trimester. However, exposure is greater during the third trimester with boosting than in non-pregnant adults without boosting, and trough concentrations achieved during the third trimester were adequate for patients without PI resistance mutations.  <u>Dosing in Pregnancy:</u> • Use of unboosted FPV or once-daily FPV with RTV boosting <b>is not recommended</b> during pregnancy. No change <b>is indicated</b> in standard boosted twice-daily dose (FPV 700 mg plus RTV 100 mg twice daily without food).	Low placental transfer to fetus. <sup>b</sup>  Insufficient data to assess for teratogenicity in humans. Increased fetal loss in rabbits but no increase in defects in rats and rabbits.  Must be given as low-dose RTV-boosted regimen in pregnancy.	June 7, 2016
<b>Indinavir</b> (IDV) <i>Crixivan</i>  <b>Note:</b> Must be combined with low-dose RTV boosting in pregnancy	<u>Capsules:</u> • 200 mg • 400 mg	<u>Standard Adult Dose</u> <i>Without RTV Boosting:</i> • IDV 800 mg every 8 hours, taken 1 hour before or 2 hours after meals; may take with skim milk or low-fat meal.  <i>With RTV Boosting:</i> • IDV 800 mg plus RTV 100 mg twice daily without regard to meals  <u>PK in Pregnancy:</u> • IDV exposure markedly reduced when administered without RTV boosting during pregnancy. IDV exposure low with IDV 400 mg/RTV 100 mg dosing during pregnancy; no PK data available on alternative boosted dosing regimens in pregnancy.  <u>Dosing in Pregnancy:</u> • Use of unboosted IDV <b>is not recommended</b> during pregnancy.	Minimal placental transfer to fetus. <sup>b</sup>  No evidence of human teratogenicity in cases reported to the APR (can rule out 2-fold increase in overall birth defects).  Must be given as low-dose, RTV-boosted regimen in pregnancy.  Theoretical concern regarding increased indirect bilirubin levels, which may exacerbate physiologic hyperbilirubinemia in neonates. Minimal placental passage mitigates this concern.	June 7, 2016

**Table 8. Antiretroviral Drug Use in Pregnant HIV-Infected Women: Pharmacokinetic and Toxicity Data in Human Pregnancy and Recommendations for Use in Pregnancy<sup>a</sup>** (page 12 of 19)

Generic Name (Abbreviation) Trade Name	Formulation	Dosing Recommendations	Use in Pregnancy	Last Reviewed
Lopinavir/ Ritonavir (LPV/r) Kaletra	<p><u>Tablets (Co-Formulated):</u></p> <ul style="list-style-type: none"> <li>• LPV 200 mg plus RTV 50 mg</li> <li>• LPV 100 mg plus RTV 25 mg</li> </ul> <p><u>Oral Solution:</u></p> <ul style="list-style-type: none"> <li>• LPV 400 mg plus RTV 100 mg/5 mL</li> </ul>	<p><u>Standard Adult Dose:</u></p> <ul style="list-style-type: none"> <li>• LPV 400 mg plus RTV 100 mg twice daily, or</li> <li>• LPV 800 mg plus RTV 200 mg once daily</li> </ul> <p><u>Tablets:</u></p> <ul style="list-style-type: none"> <li>• Take without regard to food.</li> </ul> <p><u>Oral Solution:</u></p> <ul style="list-style-type: none"> <li>• Take with food.</li> </ul> <p><u>With EFV or NVP (PI-Naive or PI-Experienced Patients):</u></p> <ul style="list-style-type: none"> <li>• LPV 500 mg plus RTV 125 mg tablets twice daily without regard to meals (use a combination of two LPV 200 mg plus RTV 50 mg tablets and one LPV 100 mg plus RTV 25 mg tablet), or</li> <li>• LPV 520 mg plus RTV 130 mg oral solution (6.5 mL) twice daily with food</li> </ul> <p><u>PK in Pregnancy:</u></p> <ul style="list-style-type: none"> <li>• With twice-daily dosing, LPV exposure is reduced in pregnant women receiving standard adult doses; increasing the dose by 50% results in exposure equivalent to that seen in non-pregnant adults receiving standard doses.</li> <li>• No PK data are available for once-daily dosing in pregnancy.</li> </ul> <p><u>Dosing in Pregnancy:</u></p> <ul style="list-style-type: none"> <li>• Once daily dosing <b>is not recommended</b> during pregnancy.</li> <li>• Some experts recommend that an increased dose (i.e., LPV 600 mg plus RTV 150 mg twice daily without regard to meals) should be used in the second and third trimesters, especially in PI- experienced pregnant women and women who start treatment during pregnancy with a baseline viral load &gt;50 copies/mL.</li> <li>• If standard dosing is used, monitor virologic response and LPV drug levels, if available.</li> </ul>	<p>Low placental transfer to fetus.<sup>b</sup></p> <p>No evidence of human teratogenicity (can rule out 1.5-fold increase in overall birth defects).</p> <p>Oral solution contains 42% alcohol and 15% propylene glycol and is not recommended for use in pregnancy.</p> <p>Once-daily LPV/r dosing is not recommended during pregnancy</p>	October 26, 2016

**Table 8. Antiretroviral Drug Use in Pregnant HIV-Infected Women: Pharmacokinetic and Toxicity Data in Human Pregnancy and Recommendations for Use in Pregnancy<sup>a</sup>** (page 13 of 19)

Generic Name (Abbreviation) Trade Name	Formulation	Dosing Recommendations	Use in Pregnancy	Last Reviewed
<b>Nelfinavir</b> (NFV) <i>Viracept</i>	<u>Tablets:</u> <ul style="list-style-type: none"> <li>• 250 mg</li> <li>• 625 mg (tablets can be dissolved in small amount of water)</li> </ul> <u>Powder for Oral Suspension:</u> <ul style="list-style-type: none"> <li>• 50 mg/g</li> </ul>	<u>Standard Adult Dose:</u> <ul style="list-style-type: none"> <li>• 1250 mg twice daily or 750 mg three times daily with food</li> </ul> <u>PK in Pregnancy:</u> <ul style="list-style-type: none"> <li>• Lower NFV exposure in third trimester than postpartum in women receiving NFV 1250 mg twice daily; however, generally adequate drug levels are achieved during pregnancy, although levels are variable in late pregnancy.</li> </ul> <u>Dosing in Pregnancy:</u> <ul style="list-style-type: none"> <li>• Three-times-daily dosing with 750 mg with food not recommended during pregnancy. No change in standard dose (1250 mg twice daily with food) indicated.</li> </ul>	<p>Minimal to low placental transfer to fetus.<sup>b</sup></p> <p>No evidence of human teratogenicity; can rule out 1.5-fold increase in overall birth defects and 2-fold increase in risk of birth defects in more common classes, cardiovascular, and genitourinary.</p> <p>Contains aspartame; should not be used in individuals with phenylketonuria.</p>	June 7, 2016
<b>Saquinavir</b> (SQV) <i>Invirase</i>  <b>Note:</b> Must be combined with low-dose RTV for PK boosting	<u>Tablet:</u> <ul style="list-style-type: none"> <li>• 500 mg</li> </ul> <u>Capsule:</u> <ul style="list-style-type: none"> <li>• 200 mg</li> </ul>	<u>Standard Adult Dose:</u> <ul style="list-style-type: none"> <li>• SQV 1000 mg plus RTV 100 mg twice a day with food or within 2 hours after a meal</li> </ul> <u>PK in Pregnancy:</u> <ul style="list-style-type: none"> <li>• Based on limited data, SQV exposure may be reduced in pregnancy but not sufficient to warrant a dose change.</li> </ul> <u>Dosing in Pregnancy:</u> <ul style="list-style-type: none"> <li>• No change in dose indicated.</li> </ul>	<p>Low placental transfer to fetus.<sup>b</sup></p> <p>Insufficient data to assess for teratogenicity in humans. No evidence of teratogenicity in rats or rabbits.</p> <p>Must be boosted with low-dose RTV.</p> <p>Baseline ECG recommended before starting because PR and/or QT interval prolongations have been observed. Contraindicated in patients with preexisting cardiac conduction system disease.</p>	June 7, 2016

**Table 8. Antiretroviral Drug Use in Pregnant HIV-Infected Women: Pharmacokinetic and Toxicity Data in Human Pregnancy and Recommendations for Use in Pregnancy<sup>a</sup>** (page 14 of 19)

Generic Name (Abbreviation) Trade Name	Formulation	Dosing Recommendations	Use in Pregnancy	Last Reviewed
<b>Tipranavir</b> (TPV) <i>Aptivus</i>  <b>Note:</b> Must be combined with RTV for PK boosting	<u>Capsules:</u> <ul style="list-style-type: none"> <li>• 250 mg</li> </ul> <u>Oral Solution:</u> <ul style="list-style-type: none"> <li>• 100 mg/mL</li> </ul>	<u>Standard Adult Dose:</u> <ul style="list-style-type: none"> <li>• TPV 500 mg plus RTV 200 mg twice daily</li> </ul> <u>With RTV Tablets:</u> <ul style="list-style-type: none"> <li>• Take with food.</li> </ul> <u>With RTV Capsules or Solution:</u> <ul style="list-style-type: none"> <li>• Take without regard to food; however, administering with food may help make the dose more tolerable.</li> </ul> <u>PK in Pregnancy:</u> <ul style="list-style-type: none"> <li>• Limited PK data in human pregnancy.</li> </ul> <u>Dosing in Pregnancy:</u> <ul style="list-style-type: none"> <li>• Insufficient data to make dosing recommendation.</li> </ul>	Moderate placental transfer to fetus reported in one patient. <sup>b</sup>  Insufficient data to assess for teratogenicity in humans. No evidence of teratogenicity in rats or rabbits.  Must be given as low-dose RTV-boosted regimen.	June 7, 2016
<b>Entry Inhibitors</b>				
<b>Enfuvirtide</b> (T-20) <i>Fuzeon</i>	<u>Injectable:</u> <ul style="list-style-type: none"> <li>• Supplied as lyophilized powder. Each vial contains 108 mg of T-20; reconstitute with 1.1 mL of sterile water for injection for SQ delivery of approximately 90 mg/1 mL.</li> </ul>	T-20 is indicated for advanced HIV disease and must be used in combination with other ARV drugs to which the patient's virus is susceptible by resistance testing.  <u>Standard Adult Dose:</u> <ul style="list-style-type: none"> <li>• 90 mg (1 mL) twice daily without regard to meals</li> </ul> <u>PK in Pregnancy:</u> <ul style="list-style-type: none"> <li>• No PK data in human pregnancy.</li> </ul> <u>Dosing in Pregnancy:</u> <ul style="list-style-type: none"> <li>• Insufficient data to make dosing recommendation.</li> </ul>	Minimal to low placental transfer to fetus. <sup>b</sup> No data on human teratogenicity.	October 26, 2016



**Table 8. Antiretroviral Drug Use in Pregnant HIV-Infected Women: Pharmacokinetic and Toxicity Data in Human Pregnancy and Recommendations for Use in Pregnancy<sup>a</sup>** (page 15 of 19)

Generic Name (Abbreviation) Trade Name	Formulation	Dosing Recommendations	Use in Pregnancy	Last Reviewed
<b>Maraviroc</b> (MVC) Selzentry	Tablets: • 150 mg • 300 mg	<p><u>Standard Adult Dose:</u></p> <ul style="list-style-type: none"> <li>• 300 mg twice daily with or without food</li> <li>• MVC must be used in combination with other ARVs in HIV-1-infected adults with only CCR5-tropic virus.</li> </ul> <p><u>Dose Adjustments:</u></p> <ul style="list-style-type: none"> <li>• Increase to 600 mg BID when used with potent CYP3A inducers: EFV, ETR, and rifampin.</li> <li>• Decrease to 150 mg BID when used with CYP3A inhibitors: all PIs except TPV/r and itraconazole.</li> </ul> <p><u>PK in Pregnancy:</u></p> <ul style="list-style-type: none"> <li>• A PK study in human pregnancy demonstrated a 20% to 30% overall decrease in AUC, but C<sub>trough</sub> exceeded the recommended minimal concentration of 50 ng/mL.</li> </ul> <p><u>Dosing in Pregnancy:</u></p> <ul style="list-style-type: none"> <li>• Standard adult dosing adjusted for concomitant ARV use appears appropriate.</li> </ul>	<p>No evidence of teratogenicity in rats or rabbits; <b>insufficient data to assess for teratogenicity in humans.</b></p> <p>MVC placental passage category should be moderate.<sup>b</sup></p>	October 26, 2016

**Table 8. Antiretroviral Drug Use in Pregnant HIV-Infected Women: Pharmacokinetic and Toxicity Data in Human Pregnancy and Recommendations for Use in Pregnancy<sup>a</sup>** (page 16 of 19)

Generic Name (Abbreviation) Trade Name	Formulation	Dosing Recommendations	Use in Pregnancy	Last Reviewed
<b>Integrase Inhibitors</b>				
<b>Dolutegravir</b> (DTG) <i>Tivicay</i>  (DTG/ABC/3TC) <i>Triumeq</i>	<u>Tablets:</u> <ul style="list-style-type: none"> <li>• 50 mg</li> </ul> <u>Triumeq:</u> <ul style="list-style-type: none"> <li>• DTG 50 mg plus ABC 600 mg plus 3TC 300 mg tablet</li> </ul>	<u>Standard Adult Dose</u> <i>ARV-Naive or ARV-Experienced (but Integrase Inhibitor-Naive Patients)</i> <u>DTG (Tivicay):</u> <ul style="list-style-type: none"> <li>• 1 tablet once daily, without regard to food.</li> </ul> <u>DTG/ABC/3TC (Triumeq):</u> <ul style="list-style-type: none"> <li>• 1 tablet once daily, without regard to food.</li> </ul> <i>ARV-Naive or ARV-Experienced (but Integrase Inhibitor-Naive) if Given with EFV, FPV/r, TPV/r, or Rifampin; or Integrase Inhibitor-Experienced</i> <u>DTG (Tivicay):</u> <ul style="list-style-type: none"> <li>• 1 tablet twice daily, without regard to food.</li> </ul> <u>PK in Pregnancy:</u> <ul style="list-style-type: none"> <li>• <b>Limited</b> PK data in human pregnancy.</li> </ul> <u>Dosing in Pregnancy:</u> <ul style="list-style-type: none"> <li>• Insufficient data to make dosing recommendation.</li> </ul>	Unknown placental transfer to fetus.  Insufficient data to assess for teratogenicity in humans. No evidence of teratogenicity in mice, rats, or rabbits.	<b>June 7, 2016</b>

**Table 8. Antiretroviral Drug Use in Pregnant HIV-Infected Women: Pharmacokinetic and Toxicity Data in Human Pregnancy and Recommendations for Use in Pregnancy<sup>a</sup>** (page 17 of 19)

Generic Name (Abbreviation) Trade Name	Formulation	Dosing Recommendations	Use in Pregnancy	Last Reviewed															
<b>Elvitegravir</b> (EVG) <i>Vitekta</i>  <b>Elvitegravir/ Cobicistat/ Emtricitabine/ Tenofovir Disoproxil Fumarate</b> (EVG/COBI/ FTC/ TDF) <i>Stribild</i>  <b>Elvitegravir/ Cobicistat/ Emtricitabine/ Tenofovir Alafenamide</b> (EVG/COBI/FTC/ TAF) <i>Genvoya</i>	<u>EVG Tablet (Vitekta):</u> • 85 mg • 150 mg  <u>Tablet (Stribild):</u> • EVG 150 mg plus COBI 150 mg plus FTC 200 mg plus TDF 300 mg  <u>Tablet (Genvoya):</u> • EVG 150 mg plus COBI 150 mg plus FTC 200 mg plus TAF 10 mg	<u>Standard Adult Dose (Vitekta):</u> • EVG (as Vitekta) must be used in combination with an HIV PI co-administered with RTV and another ARV drug.  <b>Recommended Elvitegravir Dosage Taken Once Daily with Food (All Drugs Administered Orally)</b> <table><tr><th>Dosage of Elvitegravir</th><th>Dosage of Concomitant PI</th><th>Dosage of Concomitant RTV</th></tr><tr><td rowspan="2"><b>85 mg once daily</b></td><td>ATV 300 mg once daily</td><td>100 mg once daily</td></tr><tr><td>LPV 400 mg twice daily</td><td>100 mg twice daily</td></tr><tr><td rowspan="3"><b>150 mg once daily</b></td><td>DRV 600 mg twice daily</td><td>100 mg twice daily</td></tr><tr><td>FPV 700 mg twice daily</td><td>100 mg twice daily</td></tr><tr><td>TPV 500 mg twice daily</td><td>200 mg twice daily</td></tr></table> <u>Standard Adult Dose (Stribild and Genvoya):</u> • One tablet once daily with food.  <u>PK in Pregnancy:</u> • PK studies in human pregnancy limited to case report of 1 woman.  <u>Dosing in Pregnancy:</u> • Insufficient data to make dosing recommendation.	Dosage of Elvitegravir	Dosage of Concomitant PI	Dosage of Concomitant RTV	<b>85 mg once daily</b>	ATV 300 mg once daily	100 mg once daily	LPV 400 mg twice daily	100 mg twice daily	<b>150 mg once daily</b>	DRV 600 mg twice daily	100 mg twice daily	FPV 700 mg twice daily	100 mg twice daily	TPV 500 mg twice daily	200 mg twice daily	<b>Insufficient</b> data are available on placental transfer of EVG/COBI.  Insufficient data to assess for teratogenicity in humans. No evidence of teratogenicity in rats or rabbits.	October 26, 2016
Dosage of Elvitegravir	Dosage of Concomitant PI	Dosage of Concomitant RTV																	
<b>85 mg once daily</b>	ATV 300 mg once daily	100 mg once daily																	
	LPV 400 mg twice daily	100 mg twice daily																	
<b>150 mg once daily</b>	DRV 600 mg twice daily	100 mg twice daily																	
	FPV 700 mg twice daily	100 mg twice daily																	
	TPV 500 mg twice daily	200 mg twice daily																	
<b>Raltegravir</b> (RAL) <i>Isentress</i>	<u>Film-Coated Tablets:</u> • 400 mg  <u>Chewable Tablets:</u> • 25 mg • 100 mg	<u>Standard Adult Dose:</u> • 400-mg film-coated tablets twice daily without regard to food. • Chewable and oral suspension doses are not interchangeable to either film-coated tablets or to each other.  <u>With Rifampin:</u> • 800-mg film-coated tablets twice daily without regard to food.  <u>PK in Pregnancy:</u> • Decreased levels in third trimester not of sufficient magnitude to warrant change in dosing.  <u>Dosing in Pregnancy:</u> • No change in dose indicated.	High placental transfer to fetus. <sup>b</sup>  Insufficient data to assess for teratogenicity in humans. Increased skeletal variants in rats, no increase in defects in rabbits.  Case report of markedly elevated liver transaminases with use in late pregnancy. Severe, potentially life-threatening and fatal skin and hypersensitivity reactions have been reported in non-pregnant adults.  Chewable tablets contain phenylalanine.	October 26, 2016															

**Table 8. Antiretroviral Drug Use in Pregnant HIV-Infected Women: Pharmacokinetic and Toxicity Data in Human Pregnancy and Recommendations for Use in Pregnancy<sup>a</sup>** (page 18 of 19)

Generic Name (Abbreviation) Trade Name	Formulation	Dosing Recommendations	Use in Pregnancy	Last Reviewed
<b>Pharmacoenhancers</b>				
<b>Cobicistat</b> (COBI) <i>Tybost</i>  <b>Elvitegravir/Cobicistat/ Tenofovir Disoproxil Fumarate/Emtricitabine</b> (EVG/COBI/ TDF/FTC) <i>Stribild</i>  <b>Elvitegravir/Cobicistat/Tenofovir Alafenamide/Emtricitabine</b> (EVG/COBI/TAF/FTC) <i>Genvoya</i>  <b>Atazanavir/Cobicistat</b> (ATV/COBI) <i>Evo<sup>o</sup>az</i>  <b>Darunavir/Cobicistat</b> (DRV/COBI) <i>Prezcobix</i>	<u>Tablet (Tybost):</u> <ul style="list-style-type: none"> <li>• 150mg</li> </ul> <u>Tablet (Stribild):</u> <ul style="list-style-type: none"> <li>• EVG 150 mg plus COBI 150 mg plus TDF 300 mg plus FTC 200 mg</li> </ul> <u>Tablet (Genvoya):</u> <ul style="list-style-type: none"> <li>• EVG 150 mg plus COBI 150 mg plus TAF 10 mg plus FTC 200 mg</li> </ul> <u>Tablet (Evo<sup>o</sup>az):</u> <ul style="list-style-type: none"> <li>• ATV 300 mg plus COBI 150 mg</li> </ul> <u>Tablet (Prezcobix):</u> <ul style="list-style-type: none"> <li>• DRV 800 mg plus COBI 150 mg</li> </ul>	<u>Standard Adult Dose</u> <i>Tybost:</i> <ul style="list-style-type: none"> <li>• As an alternative PK booster with atazanavir or darunavir: One tablet (150 mg) once daily with food.</li> </ul> <i>Stribild, Genvoya, Evo<sup>o</sup>az, Prezcobix:</i> <ul style="list-style-type: none"> <li>• One tablet once daily with food.</li> </ul> <u>PK in Pregnancy:</u> <ul style="list-style-type: none"> <li>• No PK studies in human pregnancy.</li> </ul> <u>Dosing in Pregnancy:</u> <ul style="list-style-type: none"> <li>• Insufficient data to make dosing recommendation.</li> </ul>	No data on placental transfer of COBI are available.  Insufficient data to assess for teratogenicity in humans. No evidence of teratogenicity in rats or rabbits	October 26, 2016
<b>Ritonavir</b> (RTV) <i>Norvir</i>	<u>Capsules:</u> <ul style="list-style-type: none"> <li>• 100 mg</li> </ul> <u>Tablets:</u> <ul style="list-style-type: none"> <li>• 100 mg</li> </ul> <u>Oral Solution:</u> <ul style="list-style-type: none"> <li>• 80 mg/mL</li> </ul>	<u>Standard Adult Dose as PK Booster for Other PIs:</u> <ul style="list-style-type: none"> <li>• 100–400 mg per day in 1–2 divided doses (refer to other PIs for specific dosing recommendations.)</li> </ul> <u>Tablet:</u> <ul style="list-style-type: none"> <li>• Take with food.</li> </ul> <u>Capsule or Oral Solution:</u> <ul style="list-style-type: none"> <li>• To improve tolerability, recommended to take with food if possible.</li> </ul> <u>PK in Pregnancy:</u> <ul style="list-style-type: none"> <li>• Lower levels during pregnancy compared with postpartum.</li> </ul> <u>Dosing in Pregnancy:</u> No dosage adjustment necessary when used as booster.	Low placental transfer to fetus. <sup>b</sup>  No evidence of human teratogenicity (can rule out 2-fold increase in overall birth defects).  Should only be used as low-dose booster for other PIs.  Oral solution contains 43% alcohol and therefore may not be optimal for use in pregnancy.	June 7, 2016

**Table 8. Antiretroviral Drug Use in Pregnant HIV-Infected Women: Pharmacokinetic and Toxicity Data in Human Pregnancy and Recommendations for Use in Pregnancy<sup>a</sup>** (page 19 of 19)

<sup>a</sup> Individual antiretroviral drug dosages may need to be adjusted in renal or hepatic insufficiency (for details, see [Adult Guidelines, Appendix B, Table 7](#)).

<sup>b</sup> Placental transfer categories—Mean or median cord blood/maternal delivery plasma drug ratio:

**High:** >0.6

**Moderate:** 0.3–0.6

**Low:** <0.3

<sup>c</sup> See [Teratogenicity](#) for discussion of EFV and risks in pregnancy.

<sup>d</sup> WHO recommends maximum dose of 30 mg twice daily regardless of weight.

**Key to Abbreviations:** 3TC = lamivudine; ABC = abacavir; ARV = antiretroviral; ATV = atazanavir; AUC = area under the curve; AZT = zidovudine; BID = twice daily; CD4 = CD4 T lymphocyte; CI = confidence interval; CNS = central nervous system; COBI = cobicistat; d4T = stavudine; ddI = didanosine; DTG = dolutegravir; DRV = darunavir; EC = enteric coated; ECG = electrocardiogram; EFV = efavirenz; ETR = etravirine; EVG = elvitegravir; FDA = Food and Drug Administration; FPV/r = fosamprenavir/ritonavir; FTC = emtricitabine; HBV = hepatitis B virus; IDV = indinavir; IV = intravenous; LPV = lopinavir; LPV/r = lopinavir/ritonavir; MVC = maraviroc; NFV = nelfinavir; NNRTI = non-nucleoside reverse transcriptase inhibitor; NRTI = nucleoside reverse transcriptase inhibitor; NVP = nevirapine; PI = protease inhibitor; PK = pharmacokinetic; RAL = raltegravir; RPV = rilpivirine; RTV = ritonavir; SQ = subcutaneous; SQV = saquinavir; **TAF = tenofovir alafenamide**; TDF = tenofovir disoproxil fumarate; TID = three times a day; TPV = tipranavir; TPV/r = tipranavir/ritonavir; T20 = enfuvirtide; WHO = World Health Organization; ZDV = zidovudine